The Children's Hospital
Kids Need A Kids' Hospital

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20857

Pediatric Infectious Diseases
1056 East 19th Avenue B055
Denver, Colorado 80218-1088

303 861-6981
Fax 303 837-2707

Re: Docket Number 2005D-0334

Dear Sirs:

I have reviewed the provisions of the Draft Guidance for Industry on the Pediatric Research Equity Act. The guidance appears to satisfactorily fulfill the spirit and intent of the Pediatric Research Equity Act. The provisions provide flexibility for industry, even as they encourage necessary pediatric studies.

From the perspective of a pediatric specialist and a pediatric researcher, it is imperative that the agenda for evaluation of pharmaceuticals in children of all ages proceeds. Moreover, a key provision of the guidance which must be an emphasized requirement when working with industry is the development of age-appropriate formulations. Pediatric HIV infection is but one example where this issue has heretofore not been satisfactorily addressed. Pharmaceutical manufacturers should be required, to the extent that it is chemically feasible, to develop formulations that provide maximal flexibility for children and to undertake the clinical studies that support their licensure. Implicit in this is the development of *palatable* liquid formulations that do not require administration of excessive volumes for small children and solid pediatric formulations that are *reasonable in size and dose-appropriate* for older children of varying sizes.

Your efforts on behalf of the needs of children and the pediatric community are appreciated.

Sincerely,

Mark J. Abzug, MD
Professor of Pediatrics (Pediatric Infectious Diseases), Univ. of Colorado School of Medicine
Medical Director, The Children's Hospital Clinical Trials Organization

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University of Colorado Health Sciences Center